Using Colleagues as Subjects

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The CP Study

- The CP study is designed to assess the effects of high level allergens in subjects with allergic asthma.
- Study procedures include EKG, allergy skin testing, several blood draws, and bronchoprovocation.

Bronchoprovocation

- Bronchoprovocation involves the controlled administration of a stimulus to induce airway constriction.
- Subjects in the CP study receive provocation with allergen, methacholine, and cold dry air.

Research bronchoprovocation

- Allergen bronchoprovocation is a well recognized research technique.
- It allows investigators to study the activation of peripheral blood basophils.

Safety Guidelines for Bronchoprovocation

- Monitor pulmonary function.
- Stop the procedure when a subject has a moderate drop in airflow ($\geq$ 20% drop in FEV1).
- A 20% drop in airflow is mild and typically does not cause wheezing.

Risks

- Bronchoprovocation can cause asthma attacks and, rarely, severe allergic reactions.
- Some subjects experience more substantial drops in airflow (>35% drop in FEV1).
- These subjects experience wheezing and chest tightness.

Subject Selection

- The study endpoint (basophil activation) is difficult to measure.
- Therefore, enrolling subjects with a high *in vitro* basophil response increases the value of the data.

B.F.

- "B.F." is a 29 y.o. white female with an M.S. in biology.
- She has worked in the lab for 6 years, and currently is supervised by the principal investigator of the CP study.

B.F.'s Basophils

- B.F. has an unusually high *in vitro* basophil response, making her an excellent candidate for the CP study.
- BF asked whether she could participate in the CP study.

Consult Request

The principal investigator is concerned about the appropriateness of enrolling a colleague in the CP study, and calls a bioethics consult.

Consult Process

- The bioethics team meets with B.F., independent of the research team.
- B.F. states that she wants to participate, will withdrawal if she changes her mind, and understands the risks.

The P.I.

- The P.I. feels confident that B.F. would say "no" if she did not want to participate in the CP study.
- He reports that she has been comfortable refusing blood draws requested of her in the past.

Bioethics Feedback

- The bioethics consultants conclude B.F. understands the study well, and is not being pressured to participate.
- However, they point out that maintaining confidentiality in the lab may be difficult, and participation might adversely affect B.F.'s relationship with the team.

Ethics Committee

- Given these concerns, the bioethics consultants recommend that the PI solicit input from the C.C. Ethics Committee.
- The PI presents the case to the Clinical Center Ethics Committee.

Reasons to include B.F.

- Increases the quality of the data.
- Saves time in finding quality subjects.
- B.F. understands the study's risks and requirements extremely well.
- B.F., a co-author on any resulting publications, could validate her own scientific observations.

The Cons of B.F.'s Participation

- B.F. may be feeling pressure at some level to participate.
- It might *appear* that B.F. was pressured.
- Her participation might lead to "role confusion."
- Her participation might adversely affect relationships in the lab.

Ethics Committee Resolution

- "There are no clear regulatory, legal or ethical prohibitions against enrolling B.F."
- Since B.F. is in a vulnerable position, her participation calls for additional protections, especially independent consent and participation monitors.